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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/523,647 03/10/00 MURDIN

A 032931/0227

EXAMINER

HM12/1001

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FOLEY & LARDNER
3000 K STREET NW
SUITE 500
WASHINGTON DC 20007-5109

MITRA, R	
ART UNIT	PAPER NUMBER

1653
DATE MAILED: 10/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary

Application No.

09/523,647

Applicant(s)

MURDIN ET AL.

Examiner

Rita Mitra

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 10, 12-14, 19, 35, 36 are drawn to a nucleic acid molecules, encoding a protein of SEQ ID NO: 2, comprising a sequence of SEQ ID NO: 1, sequence encoding a fusion protein; vectors, host cells, and methods of producing the polypeptide, primers, probes; classified in Class 536, subclass 23.4, 24.3, 24.32; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
 - II. Claims 8, 9, 11, are drawn to a vaccine comprising a first nucleic acid that encodes a polypeptide of SEQ ID NO: 2 and a vaccine vector wherein first nucleic acid is expressed as a polypeptide; classified in Class 536, subclass 23.4, 23.53; Class 435, subclasses 69.1, 455, 252.3, and 320.1, Class 424, subclass 184.1
 - III. Claims 15-18, 23, 37, drawn to a fusion protein comprising polypeptide that comprises amino acids of SEQ ID NO: 2, a pharmaceutical composition; classified in Class 530, subclasses 350, 820, 825, class 514, subclass 12.
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- IV. Claims 20 and 25, drawn to an antibody, that binds to a polypeptide of SEQ ID NO: 2, a pharmaceutical composition; classified in Class 530, subclass 387.1; Class 424, subclass 130.1.
 - V. Claims 21, 22, 24 are drawn to a vaccine comprising a first polypeptide of SEQ ID NO: 2, a pharmaceutical composition; classified in Class 424, subclass 184.1, Class 514, subclass 12.
 - VI. Claims 26 and 28, drawn to a method for preventing or treating Chlamydia infection using nucleic acid; classified in Class 514, subclass 12, class 536, subclass 23.4.
 - VII. Claim 27, drawn to a method for preventing or treating Chlamydia infection using vaccine comprising nucleic acid; classified in Class 514, subclass 12, class 536, subclass 23.4, class 424, subclass 184.1.
 - VIII. Claim 29, drawn to a method for preventing or treating Chlamydia infection using polypeptide; classified in Class 514, subclass 12, class 530, subclass 350, 820.
 - IX. Claim 30, drawn to a method for preventing or treating Chlamydia infection using antibody; classified in Class 514, subclass 12, class 530, subclass 387.1, class 424, subclass 130.1
 - X. Claim 31, drawn to a method for detecting Chlamydia infection using nucleic acid; classified in, Class 536, subclass 23.4; Class 435, subclass 6.
 - XI. Claim 32, drawn to a method for detecting Chlamydia infection using polypeptide; classified in Class 530, subclass 350, 820; Class 435, subclass 7.1.
 - XII. Claim 33, drawn to a method for detecting Chlamydia infection using antibody; classified in Class 530, subclass 387.1; Class 435, subclass 7.1.
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- XIII. Claim 34, drawn to a method for identifying the polypeptide comprising the amino acid sequence of SEQ ID NO: 2, which induces an immune response in a mammal previously immunized with the said polypeptide; classified in Class 424, subclass 184.1, 192.1; Class 530, subclass 820.

The inventions are distinct, each from the other because of the following reasons:

Groups I, II, III, IV and V are different products. Nucleic acids, vaccines, proteins, and antibodies to the polypeptides differ with respect to their structures and physicochemical properties, therefore each product is patentably distinct.

Groups I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the protein can be made using an amino acid synthesizer.

Groups I, II and VI, VII, X are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I and II can be used on other, materially distinct process, such as in nucleic acid hybridization assay.

Groups III, V and VIII, XI, XII, XIII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the polypeptides of Group III and V can be used on other, materially distinct process, such as in the production of antibody.

Groups IV and IX, XII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group IV can be used for affinity purification, in addition to the methods of treating and detecting recited.

Groups I, II and VIII, IX, XI, XII, XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of group I and II are not necessary for the practice of claimed methods of Groups VII, IX, XI, XII and XIII. Therefore the inventions are distinct.

Groups III, IV, V and VI, VII, X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the protein of group III and V and antibody of Group IV are not necessary for the practice of claimed methods of Groups VI, VII and X. Therefore the inventions are distinct.

The protein of Group III and V are related to the antibody of group IV by virtue of being the cognate antigen necessary for the production of antibody. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein if it is a receptor. Further, a protein and its cognate antibody are structurally and functionally distinct molecules with different amino acid compositions. Therefore, the inventions are distinct.

Groups VI, VII, VIII, IX and X, XI, XII, XIII are different methods. A method of preventing or treating and a method of detecting differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must

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conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).
The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the
status of this application should be directed to the Group receptionist whose telephone number is
(703) 308-0196.



Rita Mitra, Ph.D.

September 29, 2001

Christopher S. F. Low
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